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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/198,018	11/23/1998	THOMAS W. ASTLE	130-125	1987

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EXAMINER

BEX, PATRICIA K

ART UNIT	PAPER NUMBER
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1743

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11

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application N .	T-D-11 ASTLE, THOMAS W.
	09/198,018	Examiner
	P. Kathryn Bex.	Art Unit
		1743
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>		
Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.		
<ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). 		
Status		
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>23 January 2002</u> .		
2a) <input type="checkbox"/> This action is FINAL . 2b) <input checked="" type="checkbox"/> This action is non-final.		
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4) <input checked="" type="checkbox"/> Claim(s) <u>1-30</u> is/are pending in the application.		
4a) Of the above claim(s) <u>19,20 and 24-29</u> is/are withdrawn from consideration.		
5) <input type="checkbox"/> Claim(s) _____ is/are allowed.		
6) <input checked="" type="checkbox"/> Claim(s) <u>1-18, 21-23 and 30</u> is/are rejected.		
7) <input type="checkbox"/> Claim(s) _____ is/are objected to.		
8) <input type="checkbox"/> Claim(s) _____ are subject to restriction and/or election requirement.		
Application Papers		
9) <input type="checkbox"/> The specification is objected to by the Examiner.		
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are: a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner.		
If approved, corrected drawings are required in reply to this Office action.		
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. §§ 119 and 120		
13) <input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).		
a) <input type="checkbox"/> All b) <input type="checkbox"/> Some * c) <input type="checkbox"/> None of:		
1. <input type="checkbox"/> Certified copies of the priority documents have been received.		
2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.		
3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).		
* See the attached detailed Office action for a list of the certified copies not received.		
14) <input checked="" type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).		
a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.		
15) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.		
Attachment(s)		
1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)		
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.		
4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.		
5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)		
6) <input type="checkbox"/> Other: _____.		

DETAILED ACTION

1. In view of the arguments presented in the Appeal Brief, filed January 23, 2002, the finality of the previous Office action is hereby withdrawn.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-23, 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1, recites a plurality of *thermoformed* chemical receiving wells. However, there is no support which has been cited by Applicant or found by the Examiner which supports the use of *thermoformed* chemical receiving wells. No manufacturing method for “thermally forming” or “thermoforming” the wells is disclosed in the specification or the claims.

Additionally, the claims are drawn to method of chemical compound storage *not* the formation of the wells. Same deficiency was found in claim 21.

Claim 3, recites a roll having dimensions about four inches wide by sixteen inches *long*. The specification supports a roll having dimensions about four inches wide by sixteen inches in *diameter*, see page 11, line 10. Same deficiency was found in claim 23.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-23 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 3, the use of the word "thermoformed" creates confusion and uncertainty as to what is actually meant by "thermoformed chemical receiving wells". The process of thermoforming is clearly defined and accepted within the art to mean a process to give a final shape to a thermoplastic with the aid of heat and usually pressure. Same deficiency was found in claim 21.

Claim 30, line 2, recites the limitation "indexing repetitive patterns". There is insufficient antecedent basis for this limitation in the claim. Further, it is not clear as to what applicant means by "repetitive patterns".

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-2, 21-23 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Guigan (USP 3,620,678).

Guigan anticipates the instant claims by teaching a method of chemical compound storage comprising providing a longitudinally extending carrier tape 1,12 having a plurality of thermoformed chemical receiving wells 3, 13, 168 and adding to each of the chemical receiving wells a chemical compound. Note: Guigan clearly teaches the use a thermoplastic material

(column 4, line 34) and heat and pressure to form the wells (column 9, lines 23-30, Fig 1-3, and 9). Guigan teaches a liquid tight sealing material 10 placed over the chemical receiving wells (column 3, lines 18-43, Fig. 3 and Fig. 18). Additionally, the sealing material being heat sealed to the carrier tape is taught at col. 4, lines 30-38. The tractor drive 150 for indexing repetitive patterns of wells is taught at Fig. 20.

8. Claims 1-2, 21-22 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Howell (USP 4,863,693).

Howell anticipates the instant claims by teaching a method of chemical compound storage comprising providing a longitudinally extending carrier tape 46 having a plurality of thermoformed chemical receiving wells 96 and adding to each of the chemical receiving wells a chemical compound via pipette 116. Howell teaches the use a thermoplastic material (column 4, line 46-47) and heat and pressure to form the wells (column 3, line 30- column 4, line 15, Fig. 1). Moreover, Howell teaches a liquid tight sealing material 56 placed over the chemical receiving wells in which a closure device 115 may be mounted to a plate to completely seal the well 96 (column 5, lines 35-39, Fig. 1). Wherein the sealing material is heat sealed to the carrier tape (column 2, lines 8-10). The tractor drive 112 for indexing repetitive patterns of wells.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 3-8, 16-18 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guigan (USP 3,620,678), or Howell (USP 4,863,693), in view of Anderson (USP 5,092,466).

Guigan and Howell as discussed previously, do not disclose repetitive matrixes with a unique identifier. However, such an identifier is considered conventional in the art, see Anderson. Anderson teaches an apparatus and method for storing samples in sealed packets 14 on a carrier strip 32. Additionally, Anderson teaches a die cutting the sealing material around the wells (column 3, lines 5-13). Anderson also disclose the step of cutting out segment along perforations of the carrier tape with attached sample (column 5, lines 7-22). Moreover, Anderson teaches repetitive matrix with a unique identifier 22, 24 (Fig. 1).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the chemical storage apparatus of Guigan or Howell with the identification means of Anderson, in order to reduce the costs of storage, inventory management, and distribution of a very large number of biological samples (col. 2, lines 17-23).

Regarding the specific material of the carrier tape, it would have been obvious to one of ordinary skill in the art to have made the carrier tape of Guigan or Howell with the

polycarbonate, polystyrene or polypropylene, in order to ensure that the carrier tape is chemically inert with respect to the substances being stored. Since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

With respect to the number of chemical receiving wells in repetitive matrixes selected from the group consisting of 8 by 12 with a spacing of 9 mm between centers and the specific dimensions of the carrier tape, etc. It would have been an obvious matter of design choice to have made the chemical receiving wells in repetitive matrixes selected from the group consisting of 8 by 12 with a spacing of 9 mm between centers of Anderson in order to increase amount of samples which are assayed. Further, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

12. Claims 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guigan (USP 3,620,678) in view of Hansen *et al* (USP 4,565,783).

Guigan does not teach the sealing material with a pressure sensitive adhesive to adhere the sealing material to the carrier tape such as to permit removal of the sealing material after adhesion to the carrier tape. Hansen *et al* do teach the sealing material with a pressure sensitive adhesive to adhere the sealing material to the carrier tape such as to permit removal of the sealing material after adhesion to the carrier tape (col. 3, lines 58-68, col. 8, lines 24-56). The lower seal layer having a low melting point (polyethylene) and upper high melting point layer (polyester) joined to the seal layer is taught by Hansen *et al* col. 8, lines 24-34. Accordingly, it

would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided in the chemical storage apparatus of Guigan, the pressure sensitive adhesive as taught by Hansen *et al* in order to prevent contamination of the device during storage and incubation (col. 2, lines 19-22).

Regarding the number of aliquots (wells) and the dimensions of the carrier tape roll, it would have been an obvious matter of design choice to include such dimensions and number of wells in the carrier tape of Guigan, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

13. Claims 9-13, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guigan (USP 3,620,678), or Howell (USP 4,863,693), in view of Tidemann *et al* (USP 5,526,935).

Guigan does teach holes 5 perforating the carrier tape between the chemical receiving wells (column 4, lines 56-57, Fig. 1). Guigan and Howell fail to teach the step of evacuating space between the seal material and the carrier tape at the time of sealing. Tidemann *et al* teach a polycarbonate carrier tape 100, 102 comprising a multi-layer sealing material 120 placed in a liquid tight seal to form a well 112. The sealing material made of polyester (column 4, line 12) and having a layer formed of ethyl vinyl acetate (column 6, line 24). Moreover, Tidemann *et al* do teach the use of an aperture 118 to apply a vacuum to the well which evacuates the space between the seal material 120 and the carrier tape 102. (column 5, line 29-30, Fig. 2). Such a step of evacuation allows for more efficient loading of the wells with components (column 5, lines 29-30). Additionally, Tidemann *et al* do teach the sealing material with a pressure sensitive

adhesive or heat-sealing means to adhere the sealing material to the carrier tape such as to permit removal of the sealing material after adhesion to the carrier tape.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the method of Guigan or Howell, with the step to evacuate the space between the seal material and the carrier tape, as taught by Tidemann *et al* in order to allow for more efficient loading of the wells with components.

14. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guigan (USP 3,620,678), or Howell (USP 4,863,693), in view of Paquette (USP 4,159,953).

Guigan does not teach the step of removing the seal material from the carrier tape by using a heated roll. Paquette does teach a filter plate with bores 28, in which a sealing material 25 is placed over. Additionally, Paquette do teach the step of removing the sealing material via a heated stiper means 51 (column 5, lines 42-55, Fig. 3). Such a step of removing the sealing material provides for a readily reusable filter plate immediately following the removal of the seal material. Therefore there is no need to use a new filter plate (column 8, lines 10-23).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the method of Guigan or Howell, with the step to remove the seal material from the carrier tape, as taught by Paquette, in order to allow for more economical use of the carrier tape.

Response to Arguments

15. Applicant's arguments filed January 23, 2002 have been fully considered but they are not persuasive. In regard to the previous rejection of claims 1-3, 21-23 and 30 under 35 U.S.C. 102(b) as being anticipated by Guigan (USP 3,620,678), Applicant argues that Guigan does not teach wells which are thermally formed. Examiner points out that Applicant appears to believe the process of thermoforming is well-known in the art and therefore it is applicable that the specification of the prior art need not disclose what is so well known in the art, see page 3, 6th full paragraph of the Response. Additionally, the process of heat formation of the wells with a die taught by Guigan (column 9, lines 23-34). Therefore, the wells of Guigan have clearly been "thermally" formed (column 4, lines 30-39).

With respect to the previous rejection of claim under 35 U.S.C. 103(a) as being unpatentable over Guigan (USP 3,620,678) in view of Tidemann *et al* (USP 5,526,935), Applicant argues that the aperture of Tidemann *et al* is not for evacuating the space between the carrier tape and a sealing material, but rather Tidemann *et al* teach applying a vacuum to the pocket to permit more efficient loading of the pockets with components. Examiner contends the effect of the application of a vacuum to the aperture 118 would inherently evacuate the space between the carrier tape and sealing material.

Conclusion

16. No claims allowed.
17. The prior art made of record and not relied upon which is considered pertinent to applicant's disclosure are Kertz, Bisconte, Morle, and E. Findl *et al*. They are cited of interest in that they show various methods to store, process and analyze biological samples.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays, alternate Fridays from 6:00 am to 3:30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 308-4037.

The fax number for the organization where this application or proceeding is assigned is (703) 305-7718 or (703) 872-9310 for official papers prior to mailing of a Final Office Action. For after-Final Office Actions use (703) 872-9311. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

P. Kathryn Bex
P. Kathryn Bex
Patent Examiner
AU 1743
March 28, 2002

Jill Warden
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